UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

DATE: December 17, 1999

MEMORANDUM

SUBJECT: Coumaphos (PC Code 036501): HED's Response to Comments Submitted During Phase 3 (Public Comment Period). DP Barcode D261027.

FROM: Christina M. Jarvis, Risk Assessor
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INTRODUCTION:

Attached are HED's responses to comments received during the 60-day public comment period (Phase 3) for the organophosphorus insecticide coumaphos. Comments were submitted to the Agency by Bayer Corporation (F. McNamara letter, 10/29/99), and are in response to HED's Dietary and Occupational Risk Assessment Update (C. Jarvis memo, D257482, 07/09/99). Input has been provided by Nicole Paquette (toxicology), Sherrie Mason (dietary exposure), and Renee Sandvig

(occupational exposure). HED has carefully reviewed Bayer's comments and will take them into consideration when revising the risk assessment.

TOXICOLOGY:

1. Bayer's Comment:

An incorrect toxicological endpoint was used to evaluate short-term dermal exposure for spray uses. The NOAEL from the 2-day study should be used to evaluate short-term dermal exposure instead of the NOAEL from the 5-day study.

HED's Response:

The toxicity endpoint from the 5-day dermal toxicity study (NOAEL=5.0 mg/kg) should be used for risk assessment purposes instead of the toxicity endpoint (NOAEL = 20 mg/kg) from the 2-day dermal because the 5-day dermal study better characterizes the shape of the dose response for the critical effect (plasma, RBC, brain ChE inhibition). Upon closer examination of the 2-day dermal study, there was inhibition of brain cholinesterase at 10 mg/kg (8%) and 20 mg/kg (8%), but no effect occurred at 5 mg/kg. Although this decrease in brain cholinesterase activity was not statistically significant, the biological significance may be relevant because in the 2-day and 5-day exposure studies, the brain appears to be the first indication of coumaphos toxicity. Overall, there is higher level of confidence in the results from the 5-day dermal study. Support for the NOAEL comes from another 5-day dose range finding dermal study in which RBC and plasma cholinesterase were inhibited at all doses tested in females rats (lowest dose tested was 10 mg/kg).

DIETARY EXPOSURE:

2. Bayer's Comment:

In a recently submitted Bayer risk assessment (Bayer Report No. 109208, submitted to the Agency on October 28, 1999), Bayer did not include milk as a commodity because no detectable residues were found in any of the monitoring data that were reviewed.

HED's Response:

The HED dietary assessment of coumaphos was a modified Tier 2 assessment. No monitoring data were used in this assessment because the risks were below the Agency's level of concern (<100% PAD).

HED considers it inappropriate to remove milk from the dietary exposure assessment without

determining how milk as a commodity affects the potential risk. Therefore, in the revised dietary assessment, HED will incorporate milk into the assessment by using the best available monitoring data to determine how milk as a commodity affects the potential risk of dietary exposure to coumaphos. Since monitoring data will be used, the assessment is considered to be a Tier 3 probabilistic (Monte Carlo) assessment; therefore, the acute exposure will be assessed at the 99.9th percentile for that particular assessment.

3. Bayer's Comment:

Bayer states that there are no longer registered uses for sheep and goat; therefore, they should not be included as commodities in the dietary analysis.

HED's Response:

HED agrees with Bayer that since there are no longer uses for goat and sheep, it is inappropriate to include these commodities in the dietary exposure assessment; therefore, HED will not include exposure to coumaphos from goat and sheep in the revised dietary exposure assessment.

OCCUPATIONAL EXPOSURE:

4. Bayer's Comment:

The most efficient use of Bayer and EPA resources is to focus on the assessment for the dip vat and spray uses of coumaphos. These two types of uses are not only the two major uses, they are also the uses with the greatest potential for exposure.

HED's Response:

Besides the liquid spray and dip vat uses, the only other uses now remaining are dust uses. The liquids are used more than the dusts, but exposure to every formulation must be assessed. Adequate data do not exist to determine whether the use of liquids would result in a higher exposure than the use of dusts. Dust and liquid formulations have different routes of concern. For dusts, a major route of concern, besides dermal, is inhalation. For liquids, the major route of concern is primarily dermal. Without any data on dusts, exposure from the dust formulations cannot be assumed to be acceptable, if the spray and dip vat liquid exposures are acceptable.

5. Bayer's Comment:

With regard to dip vat uses, the HED occupational risk assessment assumes one person would mix and load a dip vat and recharge the dip vat on the same day. This is an incorrect assumption. Dip vats are

only very infrequently filled, generally only once every two years, with some of the more active vats being charged once a year. No one will have to refill an entire vat and then have to recharge it in the same day.

HED's Response:

HED agrees that one person would not mix and load a dip vat and then recharge it in the same day. Mixing and loading an entire dip vat will now be considered short-term (1 to 7 days) exposure and recharging a dip vat will be considered intermediate-term (one week to several months) exposure. This will be changed in the revised risk assessment.

6. Bayer's Comment:

With regard to spray uses, as required by the RED and agreed upon by Bayer in the August, 1997 meeting, the labels for all spray products limit the number of animals which can be sprayed to 100 per day at the highest spray rate and 200 a day at one half the spray rate. This spray limitation was to be maintained until the new short term toxicity study could be completed and the results used in new spray risk assessments.

HED's Response:

The new 5-day short-term toxicity study was used to determine the short-term dermal endpoint for coumaphos. The 100 cattle per day restriction on spray uses will be assessed in the revised risk assessment, since the restriction is still stated on the labels. The spray use without the 100 cattle per day restriction will also be assessed to determine if the restriction can be lifted as a result of the new endpoint determined by the short-term toxicity study.

7. Bayer's Comment:

The cancellation of Co-Ral 25% Wettable Powder eliminates scenarios (2a), (2b), (2c) and (10b). The cancellation of all sheep and goat uses eliminates scenarios (5) and (6). The voluntary cancellation of Co-Ral KRS Spray Foam eliminates scenario (7). The cancellation of the mechanical duster uses eliminates scenario (11). Thus, the risk assessments for these 8 scenarios are no longer necessary.

HED's Response:

Bayer submitted a request for voluntary cancellation of the wettable powder and unless it is withdrawn, the Agency will approve the cancellation of this registration. The cancellation will become effective on January 31, 2000. Since the Agency expects to release the revised risk assessment after this date

(February 1), and does not anticipate a withdrawal of the request for cancellation, the Agency has decided to exclude the wettable powder formulation from the risk assessments. Sheep and goat uses will be removed from the risk assessment since that use is only listed on wettable powder labels. The spray foam use was officially canceled by the Agency on July 29, 1999, about one month after the Occupational Exposure Chapter was finalized. The spray foam use will be removed for the revised risk assessment. The mechanical duster use still remains on many dust labels and will not be removed for the revised risk assessment.

8. Bayer's Comment:

Bayer also included as a comment a PHED assessment of dip vat and spray uses. A previously submitted PHED assessment (MRID 44296901) was also referred to.

HED's Response:

The previously submitted PHED assessment has been reviewed. Please refer to the document, *Review of "Reassessment of Operator Exposure and Risk for the Animal Spray and Dip Uses of Coumaphos"* (R. Sandvig memo, DP Barcode D237077). Any new PHED assessments presented in the comments have been taken into consideration for the revised risk assessment.